AUTORITÀ GARANTE DELLA CONCORRENZA E DEL MERCATO

AGCM

IC55 sector inquiry

The Markets for Hearing Aids in Italy

Executive Summary

26 March 2024

This document is published for information purposes only:

the only text in any relevant capacity remains that of the sector inquiry

attached to the closure decision

IC55

Executive summary

On 12 September 2023, the Italian Competition Authority (hereinafter, the "Authority" or "AGCM") launched a sector inquiry pursuant to article 12(2) of Law no. 287 of 10 October 1990, aimed at analyzing the markets for hearing aids in Italy. These activities concluded on 26 March 2024 with the approval of the final text on the inquiry (the "Inquiry" or "IC55"), available in its entirety on the Authority's website (www.agcm.it).

The Inquiry was motivated by the fact that hearing aids can constitute a significant expense, both for individual consumers as well as for the Italian National Health System (*Sistema Sanitario Nazionale*, "SSN"), when called upon under current legislation concerning Essential Care Levels (*Livelli Essenziali di Assistenza*, "LEA") to cover at least part of the purchase costs.

The aim was also to investigate, on the one hand, the potential difficulties experienced by consumers in finding the necessary information to better guide their purchasing choices and, on the other hand, the role of procurement tenders held by competent administrations within the SSN or the Regional Health Systems (*Sistemi Sanitari Regionali*, "SSR") regarding the supply of hearing aids.

Products and manufacturers

The impact of the product being investigated in the Inquiry on the lives of consumers is significant. Hearing aids amplify and transmit sound to the ear to improve auditory function: they thus solve or at least mitigate symptoms of deafness or hearing loss[1]. Hearing loss problems are extremely common throughout the population and expected to become even more widespread given the changes in lifestyles (increasingly continuous and close exposure to sound sources since a young age), as well as the increase of the elderly population and corresponding age-related hearing loss (or presbycusis).

According to recent estimates by the World Health Organization (WHO), hearing loss currently affects more than 1.5 billion people, or 20% of the world's population: at the national level, ministerial sources indicate that at least 7 million Italians, or more than 12% of the population, have hearing problems, with significant percentages among those aged between 61 and 80 (up to 25%) and the over-80s (up to 50%).

The Inquiry has, first and foremost, made it possible to better understand the product characteristics of a hearing aid and the structure of the markets along the manufacturing and distribution chain.

Hearing aids are technologically sophisticated medical devices, now completely digital. The sector's technological development is concentrated in the activities of a few, globally active, groups. These groups, in addition to their frequent use of various commercial brands, have developed significant vertical integrations with the distribution phase, through the control of retail chains: as is the case of Sonova (owner, amongst other things, of the Phonak and Audionova brands), Demant (with the Oticon brand), WS (with the Signia, Widex and Siemens brands), GN ReSound and Starkey.

The software component of the product is the predominant factor because, in the interface with increasingly light and miniaturized hardware, it can be programmed to define – even starting from a single "platform" – a wide range of versions intended for sale.

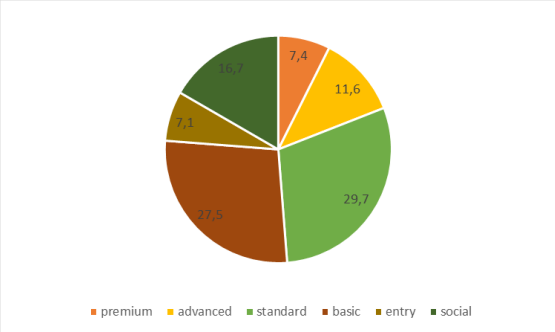
Indeed, hundreds of models are available for sale to the public, which can be differentiated by, among other aspects, industrial model criteria and "wearability" (*Behind The Ear* - BTE; *Receiver In Canal* - RIC; *In the Ear* - ITE), depending on the technological categories used by

[1] According to a shared international classification, hearing loss can be classified as: mild (in the case of a hearing threshold from 20 to less than 35 dB), moderate (with a hearing threshold from 35 to less than 50 dB), moderately severe (from 50 to less than 65 dB), severe (from 65 to less than 80 dB), profound (from 80 to less than 95 dB) or complete (95 dB and higher).

manufacturers. With regard to Italy, the reference categories are as follows, in order of increasing scale of performance and price: *(1)* Social (corresponding to those provided by the SSN/SSR to individuals); *(2)* Entry; *(3)* Base; *(4)* Standard; *(5)* Advanced; *(6)* Premium.

Below is a graph showing how sales of hearing aids to Italian consumers break down by the categories indicated above.

Type of hearing aid sold in Italy (2022 data).



Most of the hearing aids purchased in Italy are from the medium-low technological categories, with over 15% of "social" hearing aids and almost two thirds of the initial/basic/standard category; only a minority, less than 20%, is of the most advanced technological categories.

Distribution in Italy and retail prices

The Italian market for hearing aids is one of the largest in Europe in terms of both value and volume, with an estimated revenue of approximately 875 million euro and more than 500,000 hearing aids sold each year.

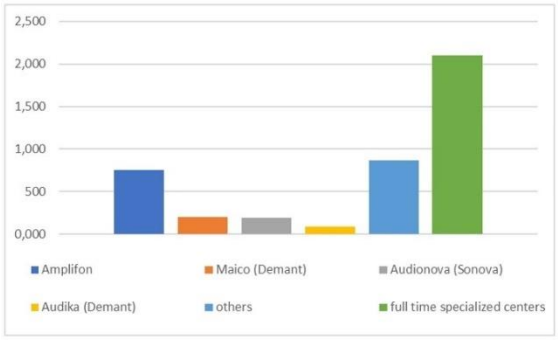
The offer is distributed widely, with about 6,000 points of contact throughout the country, between hearing centers, so-called "shop-in-shop" formulas (i.e. in shops where consumers who are particularly interested in the product can be intercepted, such as pharmacies and opticians) and contact (address) details, covering over 90% of Italian municipalities. There are about 2,100 specialist hearing centers with full-time operations.

Amplifon is the main Italian operator and is well established in various other markets in Europe, the Americas and Asia, with a network of over 750 specialist centers. Amplifon, which is not a manufacturer of hearing aids, distributes these devices made by the world's leading manufacturers under its own brand. Some commercial chains of sales points also operate in Italy, which, as mentioned above, are vertically integrated with the main manufacturers: this is the case of AudioNova-Sonova, with over 190 hearing centers, Audika-Demant and Maico-Demant, with 80 and 200 sales points respectively.

About half of the specialist hearing centers are then owned by individuals, often independent hearing care specialists who source from 2-3 manufacturers without exclusive constraints and – a distinctive feature in Italy compared to

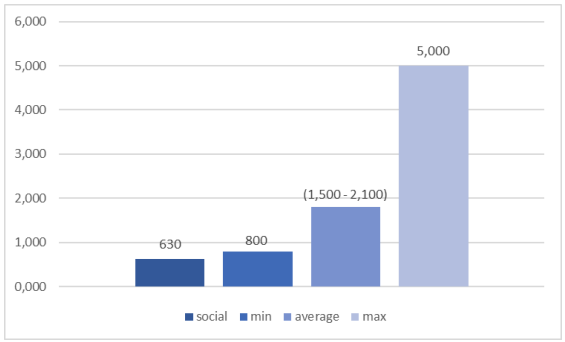
other countries – do not participate in purchasing groups.

Specialist hearing centers in Italy



The Inquiry showed that in Italy the average price of a single hearing aid is approximately 1,500-2,100 euro: price variability is wide, with a minimum price of one hearing aid equal to 630 euro for the "social" category, i.e. corresponding to the average reimbursement made by the SSN/SSR, and a maximum of 5,000 euro for the most expensive versions in the premium category.

Variability of the prices of hearing aids in Italy



Price comparisons with other countries

Regarding the pricing across different European national markets, there exists a diverse landscape characterized by notable discrepancies in both wholesale and retail prices of hearing aids. This is due to the effect of a large number of factors, starting with differences in public reimbursement mechanisms (which, with regard to Italy, will be explained in detail in section B, below). Without prejudice to this variability, it is, in any case, interesting to consider the prices of the French market, which is comparable with the Italian market in terms of population, the role of retail distribution, and certain profiles for the role of public reimbursements: indeed, in both countries, all the hearing aids are sold by private retail operators, including those for which reimbursement is provided, either fully or partially.

This comparison shows that the average prices for hearing aids in Italy tend to be higher than those seen in the French market. In fact, in France, the average price for a hearing aid is approximately 950 euro for category I hearing aids (fully reimbursed by the national health system) and approximately 1,530 euro for category II hearing aids (not reimbursable or only partially reimbursable).

A comparison with other foreign markets is decidedly less easy because, in addition to the considerable range of prices in the various markets, there are differences in organizational structure and the role of the public sector, which make it difficult

to interpret the relevant data. Indicatively, typical price ranges can still be estimated in comparative analyses (2019 data) for countries such as Germany (with prices between 830 and 3,920 euro), the United Kingdom (between 600 and 4,150 euro), and the USA (between 461 and 2,767 euro, or between 923 and 3,690 euro depending on the source).

In this regard, it should be noted that the varying price range observed across different countries, including Italy, mirrors disparities in the composition of hearing aid packages and services available in the market. This is predominantly due to the widespread adoption of a "package" sales model (bundling) by both major retail chains and independent centers. These packages include the hearing aid, customization (fitting), and after-sales (follow-up) services with the payment of a single price that includes all these components.

Distinction between device and services

The cost of the hearing aid itself has a minor influence on the final price of the package compared to the service component. Based on estimated percentages, in Italy the breakdown is approximately 20-30% for the hearing aid and 70-80% for the services.

An indication of this is, among other things, the fact that, compared to an average market price estimated at about 1,500-2,100 euro, the unit revenue related to the hearing aid sold by manufacturers in Italy, in 2022, was about 210 euro.

With reference to Italy, it is also crucial to underscore the pivotal role of the hearing care specialists within the hearing aid market. This profession is defined and regulated by a State regulation (Italian Ministerial Decree 668/1994) that concerns the selection, supply, adaptation, and control of hearing aids, that is, all the services required for the customization and proper functioning of the devices; furthermore, in the specific case of hearing aids provided by the Italian national health system, current legislation (article 17(3)(b) of Italian Presidential Decree of 12 January 2017) provides that the fitting of a device must be done by a hearing care specialist. If, therefore, the sale and purchase of the device remains free for the consumer in Italy, its fitting is regulated by the intervention of a professional technician.

However, technological innovation is profoundly reshaping the provision of technical services and device management services, consequently influencing the scope of activities undertaken by hearing care specialists. Indeed, with the advent of digital technologies, diagnosing and measuring a user's activities, as well

as fitting and follow-up interventions, are done with software programs. This offers the opportunity, on the one hand, for at least some types of services to be provided remotely by the hearing care specialist and, on the other hand, for certain adjustments and modifications to be made directly by the users of the devices themselves, usually through an app installed on their smartphone.

Beyond the preliminary stages of these transformations, encompassing shifts in usage patterns, this technological advancement is poised to reshape the future landscape of markets. Evidence of this can be observed through recent developments abroad, such as the introduction of *Over-The-Counter* ("OTC") hearing aids in the USA, marketed through broader distribution channels, catering to users with mild to moderate hearing impairments. Concurrently, in Europe, there is a growing trend of hearing aid sales via online platforms. The increasing diversification of the services component compared to the device itself emerges as a significant issue highlighted in the Inquiry findings. The subsequent pages encapsulate the conclusions of the IC55 closure document, providing a comprehensive overview of these developments.

A. Analysis of the conditions of poor transparency in the offer of hearing aids to consumers, and policy proposals

Given the general mediated nature of the demand and the complexity of the product (trusted goods), in the process of selecting and purchasing a hearing aid, a series of concerns arise. These concerns stem from consumers facing challenges in accessing both technical specifications and pricing information for devices and services, particularly within a context marked by pronounced product differentiation. The recurrence of these information asymmetries is then associated, in the general practices adopted by the sector, with the use of combined product and services sales methods (bundling), found to be prevalent among both retail chains and independent hearing care centers.

These factors collectively affect the consumer's capacity to make well-informed decisions, consequently raising the risk of distorted decision-making processes or hindering opportunities for comprehensive comparisons among competing commercial offers. This includes limitations on the ability to foster demand mobility through enhanced comparability of deals. The Inquiry revealed that, notably, consumers often struggle to discern between the product and service components within the sales packages presented to them. As a formal part of the sales negotiation and purchase agreement, the offer typically remains described solely in terms of the product component, both within the contractual proposal and on the invoice.

By way of example, in quotes and invoices provided by consumer associations, detailed technical specifications for the device and its accessories are consistently provided, yet specific details regarding the services required for adaptation or adjustment are notably absent. An examination of the contractual forms provided by major retailers has substantiated this commercial practice. Moreover, a verification of the contractual forms has shown that the services component is often included in highly generic items, from which it is not possible to clearly assess the impact of this component on the price offered.

Numerous consumer advocacy groups have highlighted the challenges consumers face in realizing that their purchases encompass both the device and an extensive array of technical services, which themselves are further differentiated. These groups also note that the absence of such a distinction prevents buyers from properly assessing

the relevant tax implications, given the differential taxation rates applicable to products (4% VAT) and services (VAT exempt).

The absence of differentiation between products and services in the consumer information is notable, especially considering that, as revealed by the Inquiry, the services component accounts for the largest percentage of the price. According to breakdowns provided by various sources, this ratio typically ranges from 20-30% for the device to 70-80% for services. To facilitate a meaningful competitive comparison, it is imperative that consumers can understand and assess the various components of the deal. This requires clear information regarding the contents, nature, and key characteristics of the goods and services included in the offer. While recognizing that the current formulation of offers raises a substantial obstacle to the full development of competitive dynamics, it is essential to acknowledge that any commercial practice capable of misleading consumers regarding pricing and its calculation is likely to take on significance under the regulations on consumer protection.

Distinguishing between the product component and the services component is certainly feasible for commercial operators. The device can be readily identified based on its specifications. As regards services, various acts and documents, such as the Decree D.P.C.M 12 January 2017 (DPCM-LEA) and the guidelines for hearing care specialist technicians, have long defined the distinct phases of professional services that can be provided. Finally, a naming convention for the services provided by health care specialists is also being adopted by the relevant professional bodies.

Any effective classification of services can produce benefits in terms of market transparency in favor of consumers, with the possibility for each company to adopt its own transparent price list to be communicated to the public. At the same time, while clear and accurate communication to consumers regarding the expense items shaping the final price at the time of purchase is certainly desirable, it is important to note that this good practice should not lead to the establishment of standardized reference tariffs applicable to all operators. Indeed, according to established principles, coordinated price fixing may amount to an illegal conduct under competition law.

Once the need for this distinction between purchase items has been established, it is also advisable to provide consumers with more detailed information regarding the device's characteristics, particularly concerning its classification within a specific technical or commercial category.

As already seen, hearing aid categories have long been in use by manufacturers and commercial operators, with a range that covers products defined as entry or basic to premium, corresponding to different price ranges. It would be beneficial to have this information standardized across various operators in order to ease the comparison of product offers for consumers. To promote even greater informed consumer choice, the ability to identify correlations, at least in the first instance, between device models and hearing impairments must be explored.

The matter is sensitive due to the high degree of customization of devices, yet the experience of a prominent Italian national public pension institute (INAIL) can serve as a reference model. For years, INAIL has consistently utilized correlations between available types of devices in the market and various degrees of hearing impairments. Moreover, it should also be considered that, in the USA, the OTC sale of hearing aids designed to compensate for mild or moderate hearing impairments has recently been allowed based on a product label that expressly correlates the device model to the aforementioned impairment for a specific consumer target.

The availability of more information on the various constituent parts of the offer would allow the consumer to better understand the specific content of the offer, with a view to being able both to compare alternative offers and to consider the actual need for the services being offered and the related cost items that contribute to defining the overall final price.

Designing offers of different types, suitable for consumers with different preferences and spending abilities (for example, all-inclusive packages or combinations of items according to the price list with the option of variations over time), remains fully available to economic operators, provided that each offer complies with the requirements for transparency illustrated herein.

Taking these factors into account, the common practice of bundled (or package) sales should not inherently be viewed as detrimental to competition or consumers, as long as it follows a clear distinction between the various components of the offer. In conclusion, there is a pressing need for more comprehensive and detailed information dissemination in Italy regarding hearing aids, which should include consumer education efforts.

This becomes particularly crucial to address the existing gap in applicable regulations concerning public communications regarding medical devices, unlike the standards observed in

other markets for trusted goods that also impact the health of their users.

This education could be usefully developed, first of all, by decision-makers and public administrators, in the context of campaigns to raise awareness of the issue of hearing health, considering the growing social relevance to be recognized therein.

B. Analysis of the reimbursement conditions and public purchases of devices and policy proposals

The Inquiry showed that, in Italy, public demand feeds a secondary part of the hearing aid and related services market, corresponding to approximately 110 million euro (in 2022) compared to a total expenditure of approximately 875 million euro. Of all the hearing aids used nationally in the same period, public spending fully covers only 10%, in addition to the 25% reimbursed only partially on the basis of the currently applied ascribable mechanism ("riconducibilità").

The reduced impact on overall spending does not diminish the importance of public procurement policies concerning hearing aids. To be noted, these policies have undergone considerable operational challenges in recent years, primarily due to a regulatory framework that remained incomplete for a lengthy period. Consequently, the relevant administrations have been compelled to rely on outdated device classifications, which are obsolete from both technical and economic standpoints. Considering the insights gleaned from the Inquiry regarding anticipated regulatory changes affecting hearing aids, upon which the potential return of these devices to tariff reimbursement mechanisms hinges, the following observations are made.

According to the Authority's consolidated view, the tender instrument constitutes the elected method for satisfying the public need for goods and services in the pursuit of administrative transparency, efficiency of expenditure, and protection of competition, with expected benefits in terms of a better allocation of resources and an increase in the welfare of the community.

This is all the more relevant with respect to the management of public spending directed towards procuring goods and services aimed at upholding the right to health. Despite being a priority in terms of public spending, this right is inherently subject to the economic and budget constraints faced by public purchasers.

The alleged failure of the public procurement procedures implemented thus far in Italy for the supply of hearing aids, subsequent to the enactment of the DPCM-LEA in 2017, cannot, therefore, be solely relied upon as a selective criterion for excluding the tender instrument in the reference market. Where, therefore, legislative and/or regulatory changes intervene to restore the ability for public administrations to purchase according to a pre-established tariff regime, the possibility of also resorting to public tender procedures must be safeguarded for the competent administrations.

In this regard, it seems feasible to implement tender frameworks that differentiate between products and services, aiming to achieve cost savings for both purchase components. This approach should ensure the quality and variety of goods by implementing appropriate criteria for evaluating bids. It is also worth mentioning the potential to utilize procurement procedures that enable dynamic adjustments to the offer, particularly concerning the technological advancements in the relevant sector. Additionally, incorporating mechanisms aimed at safeguarding the patient's freedom of therapeutic choice could be beneficial. That said, even where the possibility of resorting to a tariff mechanism is provided for, the adoption of pro-competitive solutions should be employed that, on the one hand, aim at efficiency in public spending and, on the other hand, allow for more effective selections of the products and services provided to individuals. In this regard, to enhance market transparency and facilitate the comparison of offers for the portion of demand eligible for public contributions, it is conceivable to reconsider the payment methods for public contributions. Currently, these contributions are directly paid by the competent administration to the seller of the product-service package chosen by the patient (whether social or through the ascribable mechanism).

This proposed change could make the reimbursement amount directly assigned to the patient through the introduction of a fractionable voucher or a "hearing coupon", encompassing both the product and service components. This solution would empower consumers interested in actively researching and evaluating offers within the specified reimbursement limit, allowing them to independently allocate the disbursed amount across various items based on their individual needs. Meanwhile, consumers less inclined to engage in commercial research activities could opt for conventional all-inclusive social offers, such as those traditionally provided by companies.

While recognizing the need for thorough analysis by competent decision-makers, the implementation of a voucher mechanism could effectively bolster competition among product and service suppliers, ensuring the suitability and economic benefits of the offer for individual recipients of public reimbursement. This approach aims to optimize the utilization of the limited public resources available to address individual health concerns affecting millions of individuals, which also have significant social implications.

With the same goal of optimizing the use of limited economic resources, ensuring cost savings, and enhancing healthcare quality, it is important to acknowledge that, alongside the anticipated regulatory modifications and revisions following the implementation of the 2023 Tariff Nomenclature, competent decision-makers will need to update the technical specifications of hearing aids covered by the LEA Essential Care Levels regime. Additionally, they should establish a mechanism for periodic review of these updates.

This approach enables the integration of technological innovations that characterize the reference markets and facilitates the abandonment of the outdated 1999 Tariff Nomenclature and an ascribable system, where the characteristics of devices eligible for reimbursement are unclear and inconsistent.

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